IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number	:	10/599,020	Confirmation No.:	3183
Applicant	:	BEN et al.		
Filed	:	September 18, 2006		
Title	:	USE OF A CATALYTIC SYSTEM FOR LACTIDE AND GLYCOLIDE (CO)OLIGOMERIZATION		
TC/Art Unit		1796		
Examiner:		Gregory Listvoyb		
Docket No.	:	58767.000017		
Customer No.	:	**21967**		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION FOR THREE-MONTH EXTENSION OF TIME, AMENDMENT AND RESPONSE UNDER 37 C.F.R. § 1.111

Sir:

Applicant submits the following claim amendments and remarks in response to the Office Action mailed July 8, 2011. Applicant respectfully petitions for a three-month extension of time within which to submit a response, thereby extending the period up to and including January 9, 2012, since January 8, 2012 falls on a Sunday. Please charge the undersigned's **Deposit Account No. 50-0206** in the amount of $1,270.00 to cover the three-month extension of time fee. It is believed that no additional fees are required for entry of these remarks, but should any additional fees be necessary to enter this response, the USPTO is authorized to charge such fees to Deposit Account No. 50-0206.

In the Claims begins on page 2 of this paper.

Remarks begin on page 5 of this paper.

In the Claims:

This listing of claims will replace all prior versions and listings of the claims.

1 – 15. **(Canceled).**

16. **(Currently Amended)** A catalytic system comprising:

(a) a strongly acidic ion-exchange resin polymeric catalyst[,]; ~~and~~

(b) a (co)oligomerization additive of general formula (2)

$$R^1—E—R^2 \qquad (2)$$

wherein:

E represents an element of group 16;

R^1 represents a hydrogen or deuterium atom;

R^2 represents a hydrogen or deuterium atom, or a group of formula $-E_{14}(R_{14})(R'_{14})(R''_{14})$;

wherein:

E_{14} is an element of group 14;

R_{14}, R'_{14} and R''_{14} represent, independently, a hydrogen atom; a deuterium atom; or a substituted or non-substituted alkyl, cycloalkyl or aryl,

wherein said substituent or substituents comprise: halos, hydroxys, alkyls, alkoxys, cycloalkyls, cycloalkoxys, aryls, aryloxys, carboxys, alkoxycarbonyls, cycloalkoxycarbonyls and aryloxycarbonyls or mixtures thereof; **and**

(c) ~~for the (co)oligomerization of~~ lactide and/or glycolide ~~by ring opening~~**monomers;**

wherein the quantity of monomer relative to the quantity of (co)oligomerization additive ranges from 2 to 30 molar equivalents and the conversion of monomer is greater than 95%.

17. **(Canceled).**

18. **(Previously presented)** The catalytic system of claim 16, wherein the quantity of monomer relative to the quantity of (co)oligomerization additive ranges from 4 to 10 molar equivalents.

19. **(Previously presented)** The catalytic system of claim 16, wherein the polymeric catalyst comprises a styrene and divinylbenzene-based macroreticular resin with sulfonic acid functions.

20. **(Previously presented)** The catalytic system of claim 16, wherein the polymeric catalyst comprises a macroreticular Amberlyst® or Dowex® resin.

21. **(Previously presented)** The catalytic system of claim 20, wherein the polymeric catalyst comprises an Amberlyst® resin.

22. **(Previously presented)** The catalytic system of claim 16, wherein the compound of general formula (2) is such that

E represents an oxygen or sulfur atom;

R^1 represents a hydrogen atom;

R^2 represents a hydrogen atom or a group of formula $-E_{14}(R_{14})(R'_{14})(R''_{14})$;

wherein E_{14} is a carbon or silicon atom;

R_{14}, R'_{14}, and R''_{14} represent, independently, a hydrogen atom, or substituted or non-substituted alkyl, cycloalkyl or aryl,

wherein said substituent or substituents comprise: halos, alkyls, cycloalkyls, phenyls, naphthyls, carboxys and alkoxycarbonyls or mixtures thereof.

23. **(Previously presented)** The catalytic system of claim 16, wherein the compound of general formula (2) is such that

E represents an oxygen atom;

R^1 represents a hydrogen atom;

R^2 represents a hydrogen atom or a group of formula $-E_{14}(R_{14})(R'_{14})(R''_{14})$;

wherein E_{14} is a carbon atom;

R_{14}, R'_{14}, and R''_{14} represent, independently, a hydrogen atom, or a substituted or non-substituted alkyl radical

wherein said substituent or substituents comprise: alkyls, carboxys, and alkoxycarbonyls, or mixtures thereof.

24. **(Previously presented)** The catalytic system of claim 16, wherein the compound of general formula (2) is such that

E represents an oxygen atom;

R^1 represents a hydrogen atom;

R^2 represents a hydrogen atom or a group of formula $-E_{14}(R_{14})(R'_{14})(R''_{14})$

wherein E_{14} represents a carbon atom and

R_{14}, R'_{14}, and R''_{14} represent, independently, a hydrogen atom or an alkyl radical.

25. **(Previously presented)** The catalytic system of claim 16, wherein the compound of general formula (2) comprises water or an alcohol.

26. **(Previously presented)** The catalytic system of claim 25, wherein the compound of general formula (2) comprises an aliphatic alcohol.

27. **(Previously presented)** The catalytic system of claim 26, wherein the compound of general formula (2) comprises isopropanol, pentan-1-ol, dodecan-1-ol, or mixtures thereof.

28 – 32. **(Withdrawn)**.

33. **(Cancelled)**

34. **(Previously presented)** The catalytic system of claim 16, wherein the (co)oligomerization results in a degree of polymerization is less than 30.

35. **(New)** A catalytic system comprising:

(a) a strongly acidic ion-exchange resin polymeric catalyst;

(b) a (co)oligomerization additive of general formula (2)

$$R^1—E—R^2 \qquad (2)$$

wherein:

E represents an element of group 16;

R^1 represents a hydrogen or deuterium atom;

R^2 represents a hydrogen or deuterium atom, or a group of formula $-E_{14}(R_{14})(R'_{14})(R''_{14})$;

wherein:

E_{14} is an element of group 14;

R_{14}, R'_{14} and R''_{14} represent, independently, a hydrogen atom; a deuterium atom; or a substituted or non-substituted alkyl, cycloalkyl or aryl,

wherein said substituent or substituents comprise: halos,

hydroxys, alkyls, alkoxys, cycloalkyls, cycloalkoxys, aryls, aryloxys, carboxys,

alkoxycarbonyls, cycloalkoxycarbonyls and aryloxycarbonyls or mixtures thereof; and

(c) lactide and/or glycolide monomers;

wherein the quantity of monomer relative to the quantity of (co)oligomerization additive ranges from 2 to 30 molar equivalents and the conversion of monomer is greater than 95%; and

wherein the catalytic system is capable of producing a (co)polymer where the (co)polymer comprises R2-alcohol ends; and/or the polydispersity indexes of the (co)polymer are between 1.0 and 1.4.

REMARKS

Claims 16, 18–27 and 34 are pending. Claim 16 is amended and claim 35 is new. Applicants respectfully submit that the amendments to claim 16 do not add any new matter. Support for new claim 35 may be found at least at page 7, lines 14-15; page 8 lines 5-7; and the examples. Applicants respectfully request reconsideration of the claims in light of these amendments and the following remarks.

I. *The Rejection Under 35 U.S.C. § 112, Second Paragraph Should Be Withdrawn*

Claim 16 stands rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite for the reasons set forth on page 2 of the Office Action. Specifically, the Patent Office's rejection appears to be based on the lack of antecendent basis for the "a monomer" recitation in claim 16, since the claim is directed to "a catalytic system" and the nature of the monomers is not specified. Although Applicants are not acquiescing to the Patent Office's position, and simply in an effort to expedite the prosecution of the instant application, Applicants have amended claim 1 so that the nature of the monomers is explicitly recited, even though they were implicitly recited in the claim, prior to amendment. Reconsideration and withdrawal of this rejection are therefore respectfully requested.

II. *The Rejection Under 35 U.S.C. § 103(a) Should Be Withdrawn*

Claims 16, 18-27, and 34 stand rejected under 35 U.S.C. § 103(a) over the combined teachings of U.S. Patent No. 6,355,772 to Gruber *et al.*; U.S. Patent No. 3,047,524 to Bowman; and U.S. Patent No. 4,273,920 to Nevin *et al.* for the reasons set forth on pages 3-6 of the Office Action. Applicants respectfully traverse this rejection.

Claim 16, from which all other claims depend, is directed to a catalytic system comprising the following three elements: (a) a strongly acidic ion-exchange resin polymeric catalyst; (b) a (co)oligomerization additive; and (c) lactide and/or glycolide monomers.

Applicants will demonstrate in the remarks given below, that the systems taught by Gruber, Bowman, and/or Nevin, do not teach or otherwise contemplate the claimed catalytic system because the cited references, even when combined, do not teach or otherwise contemplate (i) the use of lactide and/or glycolide; and (ii) a catalytic system that produces a polymer where the (co)oligomerization additive is part of the polymer.

According to the Patent Office, Grüber teaches the use of Amberlyst 36 and methanol as additive for the (co) oligomerization of L-lactide and D,L-lactide in Example 8. Contrary to the Patent Office's position, however, Gruber's mentions methanol only as a washing agent and not as a reagent. In other words, even though Gruber may use methanol at some point in the process he describes in Example 8, the methanol is never a part of the polymer formed. *See* Gruber at column 20, lines 65-67 ("The resin was prepared by rinsing two times with 10 volumes dry methanol, then dried for several hours Under high vacuum for several hours at 40 ° C.").

The teachings of Bowman do little to remedy the deficiencies in Gruber's teachings. Bowman describes organic polymeric compositions containing a glycolic acid monomer and an aliphatic alcohol *as separate components*. *See, e.g.*, Bowman at column 2, lines 7-9 ("When the desired melting point is reached, the polymer product may be cooled to ambient temperature and then blended with the defined alcohol."). Bowman gives no indication regarding the role of the alcohol, except that it stabilizes the characteristics of the polymer. *See id.* at column 2, lines 15-18 ("In order to completely stabilize the polymer characteristics, it is preferred to add the alcohol just before the polymer reaches the desired melting point and continue heating until that point is reached."). Applicants are not aware of even a hint in the teachings of Bowman suggesting that the alcohol becomes part of the polymer. In contrast, the a (co)oligomerization additive of the claimed catalytic system, when it is an alcohol, is indeed part of the polymer.

Applicants wonder if those of skill in the art would even turn to Bowman to supplement the Gruber's teachings for at least the following two reasons. First, Bowman does not mention the use of *any* catalytic system, let alone a catalytic system even similar to the claimed system. Instead, the glycolic acid monomer he uses to generate the polymer is polymerized thermally via condensation reaction, the reaction being driven to completion by the removal of water. Bowman at column 1, lines 55-57. And second, as the Patent Office will appreciate, Bowman polymerizes glycolic acid. The polymerization of glycolic acid and lactic acid, as the Patent Office will appreciate, proceeds through a very different mechanism than the mechanism through which glycolide and lactide are polymerized in the context of the instant application. In the claimed catalytic system, lactide and/or glycolide are polymerized via a ring-opening polymerization (ROP). Accordingly, lactic acid and/or glycolic acid are not formed, even *in situ*.

In sum, it is not clear why, and the Patent Office has not adequately articulated why, the skilled artisan would even turn to Bowman to remedy Gruber's deficiencies, knowing that the

Bowman polymerization proceeds via different mechanism; uses glycolic acid, not glycolide; and does not produce a polymer where the alcohol is a part of the polymer.

Finally, Nevin does little to remedy the deficiencies in Gruber or Bowman. Applicants respectfully submit, in fact, that Nevin appears to be nothing more than an extension of Bowman by the addition of lactic acid to his monomer mixture. Nevin discloses the co-polymerization of glycolic acid and lactic acid via the same mechanism as Bowman, namely, condensation. Nevin's reaction, like Bowman's, is driven to completion by the removal of water. *See* column 3, lines 34-37 ("Ideally, the reaction is carried out in such manner that water which is formed during the polymerization is conveniently removed, for instance by distillation."). As mentioned above, the polymerization of glycolic acid and lactic acid proceeds through a very different mechanism than the mechanism through which glycolide and lactide are polymerized in the context of the instant application. In the claimed catalytic system, lactide and/or glycolide are polymerized via a ring-opening polymerization (ROP). Accordingly, lactic acid and/or glycolic acid are not formed, even *in situ*.

In sum, it is not clear why, and the Patent Office has not adequately articulated why, the skilled artisan would even turn to Nevin to remedy Gruber's or Bowman's deficiencies, knowing that the Nevin polymerization proceeds via different mechanism; and uses glycolic acid and lactic acid, not glycolide or lactide.

Since the Patent Office appears to have failed to meet its burden with regard to establishing a *prima facie* case of obviousness based on the cited references, the rejection under 35 U.S.C. § 103(a) over those references should be reconsidered and withdrawn.

Even if the Patent Office had met its burden, as Applicants have argued previously, the instant specification discusses the criticality of having a (co)oligomerization additive, where the additive is part of the polymer. According to the instant specification, the additive "is indispensable because in the absence of such a compound . . . the (co)oligomerization reactions are much slower, lead to much smaller yields, and are not reproducible, and therefore cannot be exploited industrially." Specification, page 4. Examples 1–8 of the instant specification utilize a catalytic system similar to that of the Amberlyst 36 resin of Gruber, but differ from Gruber by the addition of the claimed (co)oligomerization additive in molar amounts, not trace amounts. In every example of the instant specification, the percent conversion of the monomer was surprisingly and unexpectedly greater than 95%. In contrast, the maximum conversion achieved

by Gruber is for a "strongly acidic ion-exchange resin polymeric catalyst" was 73.5%. The claimed catalytic system provides at least a 20% increase in conversion of the monomer (to greater than 95%) relative to prior art, which does not use the claimed (co)oligomerization additive in molar amounts and does not incorporate the claimed additive into the polymer. Based on these results, it is clear that (i) Gruber did not use a (co)oligomerization additive in its Amberlyst 36 polymerization as a conversion of only 73.5% was attained; and (2) the prior art, as represented by Gruber, did not recognize the unexpectedly beneficial effect of using a (co)oligomerization additive with the claimed catalytic system. For at least these additional reasons, Gruber alone fails to render the claimed invention obvious.

In view of the foregoing, it is believed that this application is now in condition for allowance, and a Notice thereof is respectfully requested.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 955-1500. All correspondence should continue to be directed to our address given below.

Respectfully submitted,
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